

in cartons labeled in part: "Rheumatism * * * Sciatica, Lumbago, Lamé Back, Uric and Lactic Acid Conditions, Blood Disorders, Eczema, Chronic Sores and similar affections arising from bad blood."

Analysis of a sample of the article by the Bureau of Chemistry of this department showed that the product consisted essentially of potassium iodide, extracts of plant drugs including colchicum, a trace of salicylic acid, anise flavor, glycerin, alcohol, and water.

Misbranding of the article was alleged in the libels for the reason that the bottle labels and accompanying cartons and circulars bore statements regarding the curative and therapeutic effects of the said article, which were false and fraudulent in that the article contained no ingredients or combination of ingredients capable of producing the effects claimed, and the article was insufficient of itself for the successful treatment and cure of the ailments and diseases for which it was prescribed and recommended in the said statements.

On July 18, 1923, no claimant having appeared for the property, judgments of condemnation and forfeiture were entered, and it was ordered by the court that the product be destroyed by the United States marshal.

HOWARD M. GORE, *Secretary of Agriculture.*

12652. Misbranding and alleged adulteration of coal-tar color. U. S. v. One Pound Can Coal-Tar Color. Case tried to the court without a jury. Judgment for Government. Product ordered condemned. Case carried to Circuit Court of Appeals on writ of error. Product adjudged misbranded but not adulterated. Judgment of condemnation affirmed. (F. & D. No. 14796. I. S. No. 3238-t. S. No. C-2965.)

On April 15, 1921, the United States attorney for the Eastern District of Illinois, acting upon a report by the Secretary of Agriculture, filed in the District Court of the United States for said district a libel and on July 30, 1921, an amended libel praying the seizure and condemnation of 1 pound can of coal-tar color, remaining in the original unbroken package at Waterloo, Ill., consigned by W. B. Wood Mfg. Co., St. Louis, Mo., alleging that the article had been shipped from St. Louis, Mo., on or about March 18, 1921, and transported from the State of Missouri into the State of Illinois, and charging adulteration and misbranding in violation of the food and drugs act. The article was labeled in part: "1 Lb Net W. B. Wood Mfg. Co St. Louis, Mo. Warranted Complies With All Requirements Quality Color * * * Number 810 Contents Yellow."

Adulteration of the article was alleged in the libel for the reason that sodium chloride and sodium sulphate had been mixed and packed with and substituted wholly or in part for the said article. Adulteration was alleged for the further reason that the article contained an added poisonous or deleterious ingredient, arsenic, which might have rendered it injurious to health.

Misbranding was alleged in the libel as amended in that the statement appearing on the can containing the article, "Warranted Complies With All Requirements Quality Color," was false and misleading and in that the said article was labeled so as to deceive and mislead the purchaser, and for the further reason that it was an imitation of and offered for sale under the distinctive name of another article.

On September 12, 1921, the W. B. Wood Mfg. Co. having appeared as claimant for the property and a jury having been waived, the case came on for trial before the court. After the submission of evidence and arguments by counsel, the court, on November 10, 1921, delivered the following opinion and judgment (English, D. J.):

"This suit was instituted by the Government by filing a libel charging that the particular can of coal-tar color which is libeled was shipped or transported in interstate commerce and that it remained unsold and in the original package as shipped at the time it was seized by the officers of the Government.

"It further charges that the color contained in this can was packed with or had mixed with it salt, sodium chloride, and sodium sulphate, so as to lower and reduce and injuriously affect the quality and strength of the coloring matter contained in the can. It also charges that the sodium chloride and sodium sulphate had been substituted wholly or in part for the coloring matter and that the label was not correct according to the composition of the contents of the can. It also charges that this can of coal-tar color contained an added poisonous and deleterious ingredient, arsenic, which rendered it injurious or may have rendered it injurious to health. The libel further alleges

that the statement or label borne on the can was false and misleading so as to deceive and mislead the purchaser or one seeking to buy it for use.

"This in effect states the entire charge or charges contained in the libel. This libel is based upon the statute of the United States commonly known as the food and drugs statute, and the particular section of the statute covering the questions raised and disputed in the libel are sections 8723 and 8724 of the General Statutes of the United States.

"It is shown by testimony and admitted by counsel that this particular can was put upon the market and offered for sale and purchased by the purchaser in this case for the purpose of using it in his confectionery for the coloring of ice-cream, soda water, lemonades and candy and cakes, etc; therefore, it comes under the first division referred to, which reads as follows as pertaining to coal-tar or other coloring matters for confectionery purposes: 'If it contain * * * poisonous color * * * or other ingredient deleterious or detrimental to health, or any vinous, malt, or spirituous liquor or compound or narcotic drug.' As to foodstuffs, the same section of the statute provides: 'First. If any substance has been mixed and packed with it so as to reduce or lower or injuriously affect its quality or strength.'

"These two quotations are the ones that affect the questions relative to the deterioration and also the adding of a poisonous or deleterious substance so as to make a compound that may be injurious to health. The deleterious feature in this substance appeals more strongly to the court than any other feature in the libel and upon that question I have given more thought and more attention and investigation.

"The Government introduced the parties who know how this substance is prepared or how it may be prepared, this coloring matter, and gave the court some technical information along that line and in addition introduced Doctor Boos, one of the noted specialists, both as a physician and as a chemist and a man of research, as to the feature of the alleged poisonous character of the substance found in this can. Doctor Boos appealed to the court most strongly from a practical and technical point of view, more so than any of the witnesses offered on behalf of the respondent upon this question, for the reason that the physicians who were called by the respondent testified from their observation as practicing physicians called in to administer to a patient in cases of emergency.

"I find by consulting some of the few most noted of the writers on this subject that I have been able to find, that poisonous substances of the kind here charged in this libel, to-wit, arsenic, is administered as of and out of necessity in cases of emergency, as perhaps all poisonous drugs and narcotics are, for the purpose of obtaining immediate results, and unless immediate results are had the one administering this poison draws the conclusion that there has been no effect produced at all upon the patient, but the same writers conclude that the necessary elements to be consumed by the human body contain all the various substances and poisons that would necessarily at some time or other, unless otherwise overcome, impair the vitality of the patient. The weight of opinion of these authorities appears to be that the human body already contains substantially all of the poisons of various kinds that our present state of longevity will permit and that anything of a poisonous character added to it becomes more or less deleterious to health or in effect tends to destroy or decrease the vitality of the human body. This evidently is the feature that Doctor Boos was discussing in his testimony, and we find [that] the definition given to the term deleterious not a new word. It is an old word and is taken in its ordinary meaning. I think Congress understood what it was passing upon, and that is the understanding this court has in passing upon the word deleterious. It may not be deleterious to the extent that its effect would be apparent immediately upon the one taking this substance into the system. The term deleterious means to hurt or damage, and anything that is deleterious is harmful and destroying. It is taken from the Latin word *delere*, which means to destroy; that is where we get the word deleterious—from the word destroy. A substance, therefore, that is deleterious has a tendency to destroy; if it is poisonous, it is harmful if permitted to be taken into the human body and while it is often administered by those called to relieve the sick in distress for the purpose of receiving immediate effect, such use is permitted only in emergency; otherwise Congress wouldn't deal with that feature of deleterious substances that might be utilized in coloring matter in foodstuffs. Doctor Boos says this may be deleterious, not that it will have immediate effect, but that the tendency is that it will and may have, added

to the other poisons in the system of the same character, and have effect upon the human body whereby it would decrease longevity.

"There is no reason why at this time of our great mental and physical development we need to add to our system unnecessarily more poisons than we already necessarily possess. The very air that we breathe is shown to be charged with a noxious poison known as arsenic; oftentimes the water we drink is charged with the same kind of a poison. Various other things that are necessary to be taken into the human body to sustain life are charged with similar poisons.

"This particular article about which Congress has legislated is that character of poison or character of confection or foodstuffs that are in the category pure and simple of luxuries. Congress might have had the power to have said that these confections or foodstuffs should possess absolutely no arsenic; it is shown in the evidence here that this particular color could have had extracted from it practically all of the poisonous substance contained therein that has been permitted by the department in putting out its regulations. It seems to me the department has allowed just about the maximum that should be permitted. It requires the poisonous substance to be reduced to the minimum amount that is practicable, but the amount contained in this particular can of preparation exceeded by far the amount the Government chemists have decided was best for the human system, and this they call permissible. It is true as contended by counsel for the respondent that the requirements put out by the Department of Agriculture upon this question are not the law, but they are a mighty good index for the court in passing upon these technical questions, especially so when they are of the importance and assume the dangerous magnitude that this particular preparation could reach if permitted to go unmolested.

"I am satisfied that the contention in the libel that this has in it stuff added that is deleterious, and that it is injurious or may be injurious to health when taken in the form of confections or foodstuffs, is well founded. It is not important and it is not really any of the court's business how that stuff came in there. It is argued by counsel both as to the charge of poisons contained in this preparation and the salt as well that they were necessarily used in the manufacture of this particular can of color and that therefore it has not been added. Now that might be true and yet this law is violated in the preparation of this particular can of color. Upon the question of the charge that this paint or coloring matter contains salt that destroys the effect or lessens the power or the efficiency of the coloring matter, it is argued by counsel for the respondent that this salt that is alleged to have been added or packed with the coloring matter was utilized for the purpose of precipitating the coloring matter that was in the liquid, so as it could be separated; that is, by putting salt into the liquid in which this coloring matter was formed or contained, brought about by a mixture of certain acids, this salt caused this coloring matter to go to the bottom of the vessel in which the liquid was found and then was separated and the salt remained in the color.

"As I recall the evidence given by men who testified upon the necessity of the use of salt, 30 per cent was about the maximum amount that any of them were willing to admit was necessary to the proper precipitation of the coloring matter in this liquid. The record in this case shows that there was salt to an amount of 43 per cent, which is something like 12 or 13 per cent in excess of the necessary amount. Now the court is not adopting the rule that 30 per cent salt would not be a violation of this law, but 30 per cent being the largest amount necessary to bring about the precipitation and being 12 or 13 per cent less than the amount of salt found in this particular can, necessarily leads to the conclusion that there was more salt in it than was reasonably necessary and therefore that much was added to it and the only logical conclusion is that it destroys or lessens the efficiency or the power of this color to produce its effect when mixed with other liquids.

"The demonstrations that were made before the court would teach that if we didn't already know it. Salt might be necessary to an extent, and salt as coloring matter to an extent is tolerated by the Government department, but that simply is for the purpose of permitting these men to engage in business, and it is not a guarantee it is not a violation of the law. We do have to have a standard to determine just how much or how little salt may be added to this same coloring matter and how much higher quality of coloring matter can be produced without any salt whatever; testimony shows simply by the cooling or freezing process when it is frozen or the temperature is lowered, coloring

matter goes to the bottom of the container and is more easily separated and there is no salt necessary in cases of that sort.

"The opinion of the court is that the brand or label upon this particular can was not such a branding as would advise the public or those seeking to purchase it as is required by law as to what its contents might be. The wording of this particular brand seems to be rather technical in a way and designed for the purpose of evading the spirit of this law as to branding of color. There is nothing in the law that prescribes just what the wording of the brands must be, but the spirit of the law is that goods when permitted to go on the market must be branded in a way that will not be misleading. The particular brand in this case was 'warranted comply with all requirements quality color.' As to 'all requirements,' it was argued very strenuously that such requirements meant the requirements of the Statute of the United States. Maybe it did; nevertheless that might be misleading because, as the court has indicated, it is a false brand. If it is the law of the United States, the requirements that are to be met by this brand, then this can of composition is misbranded, because it is not what it purports to be as set forth upon the brand. It appears from the evidence here that the purchaser generally knew or understood that the requirements meant the requirements of the department and not the requirements by the statute. They were buying it according to the requirements put forth in the circulars of the department.

"Therefore, the opinion of the court is:

"(1) That the can of coal-tar color libeled in this case passed in interstate commerce and remained within the jurisdiction of this court unsold and in the original and unbroken package.

"(2) That sodium chloride and sodium sulphate had been mixed and packed with the coloring matter in said can so as to lower and reduce and injuriously affect its quality and strength.

"(3) That sodium chloride and sodium sulphate had been substituted wholly or in part for quality color, which the label on the can purported the article to be.

"(4) That the can of coal-tar color libeled contained an added poisonous or deleterious ingredient, to-wit, arsenic, which may render said article injurious to health.

"(5) That the statement borne on the label of the can, to-wit, "warranted comply with all requirements, quality color," is false and misleading and labeled so as to deceive and mislead the purchaser.

"The judgment of the court is that this can is liable to seizure, and the order of court is that it be seized, condemned, and confiscated in accordance with the provisions of section 10 of the food and drugs act."

On January 4, 1923, the claimant having perfected an appeal and the case having come up before the Circuit Court of Appeals for the Seventh Circuit on a writ of error, the Circuit Court of Appeals handed down an opinion sustaining the Government on one misbranding charge and affirming the judgment of condemnation entered by the District Court, but holding that the adulteration charges were not sustained, as will more fully and at large appear from the following opinion (Evans, *C. J.*):

"Judgment was rendered in the District Court in favor of defendant in error, libelant, confiscating certain coloring material, a product of coal-tar oil, after plaintiff in error had intervened and a trial on the merits had occurred. The issues were very much narrowed by the answer which admitted the manufacture and shipment of the objectionable material. Plaintiff in error denied that the coloring material was adulterated, denied adding poisonous or other deleterious ingredients injurious to health, and denied any misbranding of the commodity. The controverted issues were resolved in favor of the Government by the trial judge, who found:

"(1) That the can of coal-tar color libeled in this case passed in interstate commerce and remained within the jurisdiction of this court unsold and in the original and unbroken package.

"(2) That sodium chloride and sodium sulphate had been mixed and packed with the coloring matter in said can so as to lower and reduce and injuriously affect its quality and strength.

"(3) That sodium chloride and sodium sulphate had been substituted wholly or in part for quality color, which the label on the can purported the article to be.

"(4) That the can of coal-tar color libeled contained an added poisonous or deleterious ingredient, to-wit, arsenic, which may render said article injurious to health.

"(5) That the statement borne on the label of the can, to-wit, "Warranted comply with all requirements, quality color," is false and misleading and labeled so as to deceive and mislead the purchaser."

"The coloring is manufactured for bakers, ice cream manufacturers, and soft drink producers, and the Government chemist found it to consist of:

Sodium chloride-----	39.14%
Sodium sulphate-----	3.61%
Tartrazine-----	30.00%
Orange II-----	16.00%
Arsenic-----	20 parts per million.
Balance—moisture and heavy metals.	

"There are two kinds of color used in food—cochineal, which is rarely used and not here involved, and aniline color, which is the result of chemical combination produced by the mixture of two coal-tar derivatives. In its preparation it is necessary to use sulphanilic acid, which contains more or less arsenic trioxide.

"The judgment is predicated on (a) the presence of arsenic, (b) too much salt, and (c) false labeling.

"Concerning the presence of the arsenic in the product, plaintiff in error contends that unless the manufacturer adds the ingredient, arsenic, he is not liable under section 7, which provides the test, 'Fifth. If it contain any added poisonous or other added deleterious ingredient which may render such article injurious to health.' Because of the word 'added,' it is urged that the finding should be in favor of plaintiff in error, for at no time was arsenic added to the coloring.

"It is further contended that the analysis fails to show arsenic in sufficient amount to render such article injurious to health.

"It is established by the evidence that the arsenic in the coloring matter is traced to sulphanilic acid, which was added to the coal-tar derivative, and without this acid there would be no arsenic, or at least none in objectionable quantities. We therefore reject this first contention, for in the manufacture of this food product the manufacturer introduced the sulphanilic acid. In other words, the acid containing the arsenic was added to the coal-tar product and therefore arsenic was 'added.'

"We are not satisfied, however, that arsenic in such quantity as to be injurious to health was present.

"The Government recognizes the impossibility of eliminating arsenic entirely. In fact, the testimony shows that the elimination of arsenic would be at most but a matter of degree. The Government certifies color when arsenic is present and when only slightly less than that found in the confiscated product.

"The evidence in the case does not present a disputed issue of fact but rather a difference between chemists over the meaning of the words 'deleterious ingredient, injurious to health.' In recognizing that a small quantity of arsenic is not injurious to health, the Government acknowledges that this term is a relative one. Arsenic is found in infinitesimal quantities in so many articles of food that it has been said that the air we breathe, the water we drink, the smoke and dust we inhale and all the foods we consume contain arsenic. If the term be an absolute one, then they would all be condemned. The quantity of arsenic found in this coloring material is so infinitesimal that when diluted as it is ordinarily used it would take years to produce 'a dose,' such as is ordinarily prescribed by physicians, 1/30 grain. In other words, one would be required to drink 150,000 bottles of soda before he would have consumed a quantity of arsenic sufficient to equal the 'dose.'

"It may be true that by further process the amount of this drug may be reduced, but complete elimination is impossible. The Congress has not assumed to define with absolute particularity what is or what is not injurious, and we cannot accept the testimony of the one witness who testified for the Government to the effect that the word 'injurious' is an absolute term. Rather do we conclude upon the testimony before us that the arsenic present in the quantity disclosed was not injurious to health.

"After mixing the two coal-tar derivatives, to which is added the sulphanilic acid, the manufacturer is confronted with the problem of eliminating the water. This is done either by freezing or by salting, or by both freezing and salting.

"As the color is invariably reduced when used, the manufacturer has found the salting method desirable because 'up to a certain limit' the addition of

salt produces a greater quantity of coloring material. It may be true that the more salt there is added, the less the user will dilute, but otherwise no injury to the product, as such, is occasioned by the presence of salt up to 40 or 50 per cent of the gross quantity. The seller gives directions to the purchaser for the dilution, which vary according to the percentage of salt.

"To reduce the salt content is expensive, but when it is reduced to a point below 5 per cent, it is (other ingredients being satisfactory) properly subject for certification by the Government (F. I. D. No. 77).

"The Government contends that shipping this coloring material containing 40 or 50 per cent of salt in interstate commerce is a violation of section 7, which reads 'That for the purposes of this act an article shall be deemed to be adulterated: * * * In the case of food: First. If any substance has been mixed and packed with it so as to reduce or lower or injuriously affect its quality or strength. Second. If any substance has been substituted wholly or in part for the article. * * * Fifth. If it contains any added poisonous or other added deleterious ingredients which may render such article injurious to health.'

"With this contention we cannot agree, unless, as here, the product is sold under a false label. In other words, we cannot accept the contention of counsel for the Government that the coloring material, weakened (but not injured) by the larger percentage of salt, violates section 7 of the act, so long as it is not labeled or sold as a certified color. In this respect, perhaps, the designation 'quality color' is also objectionable and deceptive.

"In other words, we have presented a case where a food product (coloring material) is made and its lawful sale authorized, which contains an ingredient (salt), which is harmless in itself. The quantity of the ingredient used varies with each manufacturer and the product of each single producer also varies somewhat. Aside from its influence upon the cost of production, the presence of salt has the effect of increasing the quantity of coloring material and, regardless of the percentage used (up to 50 per cent at least), it must be very greatly diluted by the user.

"Upon these facts we have no hesitancy in saying that the statute does not, nor was it intended to, give the Secretary of Agriculture any authority to fix or establish an arbitrary per cent (say 5 per cent), beyond which the manufacturer cannot go without violating this section.

"While holding that the salt content here shown does not violate section 7 of the act, no support of justification can be found therefrom for the attempt of plaintiff in error to sell its product as a certified coloring material with a salt content less than 5 per cent.

"The goods as shipped carried a label upon which appeared the following words, 'Warranted. Complies with all requirements. Quality Color. No. 810. Contents yellow.'

"Section 8 of the food and drugs act reads: 'That the term "misbranded," as used herein, shall apply to all drugs, or articles of food, or articles which enter into the composition of food, the package or label of which shall bear any statement, design, or device regarding such article * * * which shall be false or misleading in any particular, * * *. That for the purpose of this act an article shall also be deemed to be misbranded: In the case of food: * * * Second. If it be labeled or branded so as to deceive or mislead the purchaser, * * *. Fourth. If the package containing it or its label shall bear any statement, design, or device regarding the ingredients or the substances contained therein, which statement, design, or device shall be false or misleading in any particular * * *.'

"There are certain regulations or requirements of the Department of Agriculture dealing with the use of food coloring, and the Government contends, and we think justly, that the language quoted, 'Warranted. Complies with all requirements,' was intended, and would reasonably tend to convey the belief that the color was warranted to comply with the food inspection decisions of the Department of Agriculture. Our attention has not been called to any other explanation that would give effect to the word 'requirements.' Inasmuch as the color under consideration did not comply with the requirements of the Department of Agriculture for certification, there was a misstatement, a misbranding of the package, which subjected the article to confiscation.

"The judgment is affirmed."

HOWARD M. GORE, *Secretary of Agriculture.*